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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,973	12/04/2000	Nick N. Nguyen	ASP-7	3999

7590 01/07/2005

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EXAMINER
CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,973	NGUYEN ET AL.	
	Examiner	Art Unit	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This non-final action is in response to the amendment received on 10/20/2004

Remarks

1. The IDS submitted on 10/20/2004 is the same as the IDS submitted on 03/19/2004, which a copy was included in the office action dated 06/16/2004.

2. The examiner regrets withdrawing prior allowability regarding claims 5, 13 and 17-18 in the office action dated 06/16/2004.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatanaka (EP 0 321 908).

With respect to claim 1, The Hatanaka reference teaches an apparatus for vaporizing a sterilant (figure 1, 1) including the following: an inlet (figure 2, 20), an outlet (figure 1, 13), a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9) between the inlet (20) and the outlet (13), and a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) between the circuitous path (volume containing baffles 9) and the outlet (13).

With respect to claims 2-3 and 6, the Hatanaka reference teaches the following: a plurality of baffles (figure 2, the unlabeled volume containing baffles 9), the circuitous

path includes an inner tube (figure 2, unlabeled volume between 7 and outer walls of 10 and 11) positioned concentrically within an outer tube (figure 2, 2 and 3), the circuitous path includes a first portion (figure 2 that includes 14 where sterilant flows in downward direction between the inner tube and the outer tube 2 and 3) and a second portion (figure 2, volume through baffles 9 that the sterilant flows in an opposite direction), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled downward flow direction of the sterilant and flow arrows through baffles 9).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 4-5 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0 321 908).

With respect to claim 4, the Hatanaka reference discloses an apparatus that includes a portion (figure 2, unlabeled space containing 9), which increases by at least 70% or more when compared with for example, structure10 in figure 2. Depending on the desired residence time within the apparatus, minimizing or maximizing such a region is well within the scope of the artisan. The Hatanaka reference recognizes the importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the Hatanaka apparatus in order to achieve the desired mixing time.

With respect to claim 5, The Hatanaka reference teaches an apparatus for vaporizing a sterilant (figure 1, 1) including the following: an inlet (figure 2, 20), an outlet (figure 1, 13), a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9) between the inlet (20) and the outlet (13), and a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) between the circuitous path (volume containing baffles 9) and the outlet (13) having an labeled inner orifice

space connected to 10. Further, the cross-sectional area of the flow restriction (figure 2, 1, the unlabeled space immediately above the entrance point to 10 has a cross-sectional area) is no greater than about 25% of a cross-sectional area of the circuitous path immediately upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is a matter of routine experimentation such that the Hatanaka reference recognizes the importance of achieving gas with a uniform density as a result of good mixing. The residence time is based on the desired mixing of the gases. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the Hatanaka circuitous path and the flow restrictor in order to achieve the desired mixing time.

With respect to claims 7-8, the restriction flow (figure 1, 9A) of the Hatanaka apparatus is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time. The Hatanaka reference recognizes the importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. In addition, residence time depends on the dimensions of the flow restriction. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the flow restriction in the Hatanaka apparatus in order to increase residence time of the sterilant and thereby achieve the desired mixing time.

9. Claims 9-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0 321 908) in view of Nguyen et al (U.S.P.N. 6,279,622).

With respect to claims 9, 13 and 17, the Hatanaka reference discloses a method for providing a sterilant in the vapor phase (col.3, lines 24-58) including the following: creating temperature and pressure, admitting the sterilant to be vaporized, passing the sterilant through a circuitous path, then passing the sterilant through a flow restriction and passing the sterilant out of the vaporizer. Further, the cross-sectional area of the flow restriction (figure 2, 1, the unlabeled space immediately above the entrance point to 10 has a cross-sectional area) is no greater than about 25% of a cross-sectional area of the circuitous path immediately upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is a matter of routine experimentation such that the Hatanaka reference recognizes the importance of achieving gas with a uniform density as a result of good mixing. The residence time is based on the desired mixing of the gases. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the Hatanaka circuitous path and the flow restrictor in order to achieve the desired mixing time. Regarding the disclosed percentage removal of the non-vaporizable components, the Hatanaka reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor

sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

With respect to claims 9, 13 and 17, the Hatanaka reference fails to teach applying the vapor phase sterilant to a sterilization chamber. The Nguyen reference discloses applying the vapor phase sterilant to a sterilization chamber (figure 9, 110 and 115 and col.6, lines 34-36). Thus, it would have been obvious to one having ordinary skill in the art to at the time the invention was made to modify the method of Hatanaka reference to include a sterilization chamber as taught by the Nguyen reference in order to place items in the chamber under a vacuum (col.6, lines 35-36).

With respect to claims 10-12 and 14, such claims were addressed above regarding claims 2-6. See col.3, lines 24-58 in the Hatanaka reference.

With respect to claims 15-16, the Hatanaka reference discloses using liquid hydrogen peroxide (col.3, lines 18-19) such that water is a stabilizing compound for the liquid phase of the sterilant.

With respect to claim 18, the Hatanaka reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

With respect to claims 19-20, such claims were addressed above regarding claims 7-8. See col.3, lines 24-58 in the Hatanaka reference.

10. Claims 1-14 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0321908) in view of Leibold (DE 2639301).

With respect to claims 1, 5, 9, 13 and 17, the Hatanaka reference teaches a method (col.3, lines 24-58) and an apparatus for vaporizing a sterilant (1) including the following: an inlet (20), an outlet (13), a circuitous path (9), creating temperature and pressure conditions to vaporize the sterilant (col.5, lines 28-35), admitting the sterilant to be vaporized (col.6, lines 44-47, 20, and 14), passing the sterilant through a circuitous path (col.5, lines 35-57 and 9), and passing the sterilant out of the vaporizer (13). With respect to claims 1, 5, 9, 13 and 17, the Hatanaka reference fails to teach the use of a flow restriction between the circuitous path and the outlet. In addition with regard to claims 9,13 and 17, the Hatanaka reference fails to teach applying the vapor phase sterilant to a sterilization chamber. With respect to claims 1, 5, 9, 13 and 17, the Leibold reference teaches a flow restriction (7) between the circuitous path (2) and the outlet (6). Further, the Leibold reference teaches applying the vapor phase sterilant to a sterilization chamber (page 5, lines 13-14). Regarding, the cross-sectional area of the flow restriction (7 has a cross-sectional area) in the Leibold reference of being no greater than about 25% of a cross-sectional area of the circuitous path (9) immediately upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is a matter of routine experimentation. In addition, with regard to the disclosed percentage removal of the non-vaporizable components, the Hatanaka reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the

sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

As a result, it would have been obvious to one having ordinary skill in the art to modify the method and apparatus of the Hatanaka reference to include a flow restriction between the circuitous path and the outlet as taught by the Leibold reference in order to allow the apparatus to be used continuously instead of only intermittently, in a controlled manner without danger to the surrounding and personnel (abstract, lines 13-15).

With respect to claims 2-3 and 6, the Hatanaka reference teaches the following: a plurality of baffles (9), the circuitous path includes an inner tube (10) positioned concentrically within an outer tube (figure 2, space containing 9), the circuitous path includes a first portion (unlabeled arrows in the space containing 9) and a second portion (figure 2, unlabeled arrows in 10), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled arrows in 14 and unlabeled arrows in space containing 9, and unlabeled arrows in 10).

With respect to claim 4, the Hatanaka reference teaches an apparatus that includes a portion (unlabeled space containing 9), which increases by at least 70% or more when compared with (10). Depending on the desired residence time within the apparatus, minimizing or maximizing such a region is well within the scope of the artisan since Hatanaka recognizes the importance of mixing the carrier gas with the disinfection gas is crucial to producing a gas with a uniform density (col.4, lines 6-16). Note that

mixing the gases involves time and this time interval is equivalent to the residence time of the gases within the apparatus.

With respect to claims 7-8, the flow restriction (7) in the apparatus of Leibold reference is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time. On page 4, lines 1-9, the Leibold reference teaches that if a throttle or a nozzle or a valve is installed after the circuitous path and before the gas outlet of the vaporizer, then the speed of the emission of the vapor can be controlled. This statement means that depending on the intended use, if less flow rate of the vapor is desired to be emitted, then the flow restrictor will retain the vapor longer within the apparatus and the opposite is true.

With respect to claims 10-12 and 14, such claims were addressed above regarding claims 2-4 and 6.

With respect to claim 18, the Hatanaka reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

With respect to claims 19-20, such claims were addressed above regarding claims 7-8.

11. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0321908) in view of Leibold (DE 2639301) and further in view of feasey et al (U.S.P.N. 5,130,053).

With respect to claim 15, both the Hatanaka reference and the Leibold reference fail to explicitly teach adding stabilizing compounds to the liquid sterilants. However, the feasey reference discloses adding stabilizing compounds to hydrogen peroxide (col.1, lines 5-8). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of the Hatanaka reference to include stabilizing compounds as taught by the feasey reference in order to decrease the rate of decomposition of the hydrogen peroxide by contacting it with such compounds (col.3, lines 36-40).

With respect to claim16, the Hatanaka reference discloses using liquid hydrogen peroxide (col.3, lines 18-19).

Response to Arguments

12. Applicant's arguments filed 10/20/2004 have been fully considered but they are not persuasive.

On page 7 of the Remarks section, applicant argues that, "One of skill in the art would not be motivated to combine the teachings of Leibold with those of Hatanaka et al." The examiner disagrees. Adding the flow restrictor of the Leibold reference to the apparatus of the Hatanaka reference would result in the added advantage of increasing the precise control aspect of the amount of the sterilant dispensed.

On page 7 of the Remarks section, applicant argues that, "No throttle would be necessary to prevent surges and would contraindicated as it would add an unnecessary

pressure drop into the system thus reducing energy efficiency." The examiner disagrees. Adding the flow restrictor of the Leibold reference to the apparatus of the Hatanaka reference would result in the added advantage of increasing the precise control aspect of the amount of the sterilant dispensed such that design modifications, i.e., pressure drop or other problems are a matter of routine experimentation that are within the scope of the artisan.

On page 7 of the Remarks section, applicant argues that, "As can be seen, such is not necessary when the rate is controlled by the rate of drops coming out of the nozzle." The examiner disagrees. As mentioned above, adding the flow restrictor of the Leibold reference to the apparatus of the Hatanaka reference would result in the added advantage of increasing the precise control aspect of the amount of the sterilant dispensed so that any possible harm to surroundings or personnel is completely prevented. In addition, the flow restrictor of the Leibold reference gives the added advantage of storing the sterilant in case of interruptions in the supply source resulting in a continuous dispense of the sterilant.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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